510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR 807.92(C)

The Assigned 510(k) number is: k123090

Date of Summary: November 19, 2013

Common Name: BeneCheck™ Premium GLU Monitoring System and BeneCheck™ Premium PRO GLU Monitoring System

Regulatory Information: Product Code	Classification	Regulation Section	Panel
NBW; System, Test, Blood Glucose, Over-the-Counter	Class II	21 CFR 862.1345	75 – Chemistry
CGA; Glucose Oxidase, Glucose	Class II	21 CFR 862.1345	75 – Chemistry
JJX; single (specified) analyte controls (assayed and unassayed)	Class I	21 CFR 862.1660	75 – Chemistry

Applicant:

General Life Biotechnology Co., Ltd.
7F, No. 605, Rui-Guang Rd.
Neihu District
Taipei City, 114 Taiwan
Tel.: 886-2-2205-3698
Fax: 886-2-2208-0779

Contact Persons:

Primary Contact:
Mrs. Feng-Yu Lee (Correspondent for this Application)
General Life Biotechnology Co., Ltd.
c/o IVDD Regulatory Consultant
27001 La Paz Road Suite 266B
Mission Viejo, CA 92691
Tel: (949) 951-3046; Fax: (949) 951-2042
fengyulee@ivddreg.com

Alternate Only:
Jason Su
General Life Biotechnology Co., Ltd.
7F, No. 605, Rui-Guang Rd.
Neihu District
Taipei City, 114 Taiwan
Tel.: 886-2-2205-3698 ext.103; Fax: 886-2-2208-0779
jasonsu@glbiotech.com.tw

510(k) SUMMARY (Cont.)

Identification / Product Name:
BeneCheck™ Premium GLU Monitoring System (OTC setting) and BeneCheck™ Premium PRO GLU Monitoring System (POC setting)

Device Description for BeneCheck™ Premium GLU Monitoring System:

The BeneCheck™ Premium GLU Monitoring System Kit includes the following: Meter, Blood Glucose Test Strips, Control Solutions, Lancing Device and Lancets.

The BeneCheck™ Premium GLU Meters, GLU Test Strips, and Lancing Device are manufactured by General Life Biotechnology Co., Ltd. The Premium GLU Meter, when used with the Premium GLU Test Strips, quantitatively measures glucose in fresh capillary whole blood. The performance of the BeneCheck™ Premium GLU Monitoring System is verified by the Premium GLU Control Solution.

Device Description for BeneCheck™ Premium PRO GLU Monitoring System:

The BeneCheck™ Premium PRO GLU Monitoring System Kit includes the following: Meter, Blood Glucose Test Strips, and Control Solutions.

The BeneCheck™ Premium GLU and Premium PRO GLU Meters, GLU Test Strips, and Lancing Device are manufactured by General Life Biotechnology Co., Ltd. The GLU Meter, when used with the GLU Test Strips, quantitatively measures glucose in fresh capillary whole blood. The performance of the BeneCheck™ Premium GLU Monitoring System and PRO GLU Monitoring System is verified by the Control Solution.

Intended Use for BeneCheck™ Premium GLU Monitoring System:

The BeneCheck™ Premium GLU Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm and forearm. The BeneCheck™ Premium GLU Monitoring System is intended to be used by a single person and should not be shared. The BeneCheck™ Premium GLU Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of a diabetes control program.

The BeneCheck™ Premium GLU Monitoring System should not be used for the diagnosis of, or screening for diabetes, nor for neonatal use. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

The BeneCheck™ Premium GLU Test Strips are for use with the BeneCheck™ Premium GLU Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm or forearm.

The BeneCheck™ Premium GLU Control Solutions are for use with the BeneCheck™ Premium GLU Meter and BeneCheck™ Premium GLU Test Strips to verify that the meters and test strips are working together properly and that the test performs properly.

Intended Use for BeneCheck™ Premium PRO GLU Monitoring System:

The BeneCheck™ Premium PRO GLU Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm and forearm. The BeneCheck™ Premium PRO GLU Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional

510(k) SUMMARY (Cont.)

healthcare settings, as an aid to monitor the effectiveness of a diabetes control program. The system should only be used with single-use, auto-disabling lancing devices.

The BeneCheck™ Premium PRO GLU Monitoring System should not be used for the diagnosis of, or screening for diabetes, nor for neonatal use. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

The BeneCheck™ Premium PRO GLU Test Strips are for use with the BeneCheck™ Premium GLU PRO Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm or forearm.

The BeneCheck™ Premium PRO GLU Control Solutions are for use with the BeneCheck™ Premium PRO GLU Meter and BeneCheck™ Premium PRO GLU Test Strips to verify that the meters and test strips are working together properly and that the test performs properly.

Substantial Equivalence (Predicate Kit):

The BeneCheck™ Premium GLU Monitoring System and BeneCheck™ Premium PRO GLU Monitoring System is substantially equivalent to the predicate device noted below:
Device Name: OneTouch® Ultra2 Blood Glucose Monitoring System
510k No.: k053529; Device Company: LifeScan, Inc.

Summary of Device Similarities and Differences

The predicate device OneTouch® Ultra2 Blood Glucose Monitoring System and the subject devices BeneCheck™ Premium GLU Monitoring System and Premium PRO GLU Monitoring System are identical in functionality and performance. A comparison chart outlining differences and similarities between the subject device and predicate device is shown below:

510(k) SUMMARY (Cont.)

	Similarities and Differences		
Item	BeneCheck™ Premium GLU Monitoring System (New Device, OTC setting)	BeneCheck™ Premium PRO GLU Monitoring System (New Device, POC setting)	OneTouch® Ultra2 Blood Glucose Monitoring System (Predicate Device k053529)
Indications for Use	For single-patient use only, in-vitro diagnostic use only by individuals with diabetes at home	For multiple-patient use by health care professional in clinical setting	For single-patient use only, in-vitro diagnostic use only by individuals with diabetes at home; and/or multiple-patient use by health care professional in clinical setting
Test Time	*8 seconds*		*5 seconds*
Measuring Range	20-600 mg/dL		
Operating Ranges	*Temperature 50-104°F (10-40°C)* Relative Humidity: 10-90% Altitude: up to 10,000 feet Hematocrit: 30-55%		*Temperature 43-111°F (6-44°C)* Relative humidity: 10-90% Altitude: up to 10,000 feet Hematocrit: 30-55%
Memory Capacity	*360 test results*		*500 test results*
Coding	*No Coding*		*Manual selection code number*
Storage Conditions	Transportation Storage Temperature: 50-86*°F* 10-30 °C Transportation Storage Humidity: 10-90%		
Meter Dimensions	*57 x 95 x 17.5 mm*		*3.12 x 2.25 x 0.9 in* *(79 x 57.2 x 22.9 mm)*
Meter Weight	*49.7g with batteries*		*1.5 oz (42.5g) with batteries*
Unit of measure	mg/dL		
Sample type	Fresh capillary whole blood		
Sample sites	Fingertip, forearm, palm		
Sample volume	*0.9 µL*		*1µL*
Monitor	LCD display		
Backlight	*No*		*Yes*
Power Supply	*CR2032 Battery x1*		*CR2032 Battery x2*
Power Saving	*Automatic shutoff after 3 minutes of inactivity*		*Automatic shutoff after 2 minutes of inactivity*
Control Solution	3 Levels (1, 2, 3)		
Test Strip Technology	Glucose Oxidase (GOD)		
Test Principle	Electrochemical biosensor		
Sample Application	Test strip capillary draw		
Calibration	Plasma-calibrated		
PClink Feature	*N/A*		*Yes, download results using OneTouch Diabetes Management Software*

510(k) SUMMARY (Cont.)

Statement of No Differences:
For the reasons mentioned above, it can be concluded that the BeneCheck™ Premium GLU Monitoring System and Premium PRO GLU Monitoring System is substantially equivalent to the OneTouch® Ultra2 Blood Glucose Monitoring System in commercial distribution, with respect to indications for use and technology.

Technology Characteristics:

BeneCheck™ Premium GLU Monitoring System and Premium PRO GLU Monitoring System is an electronic device that utilizes the electrical characteristic technology for measuring the glucose level in human blood. A relatively small drop of blood is placed on a disposable test strip coated with Glucose Oxidase (GOD) which interacts with the software driven meter. Within eight seconds, the level of blood glucose will be shown on the digital display screen. BeneCheck™ Premium GLU Monitoring System and Premium PRO GLU Monitoring System requires only minimum of 0.9 microliter of blood for the testing, therefore it reduces the time and effort required for testing and improves the compliance of diabetic people to their testing regimens

Discussion of Non-Clinical Tests Performed:
Non-clinical tests were evaluated to establish the performance, functionality, safety and reliability of the BeneCheck™ Premium GLU Monitoring System and Premium PRO GLU Monitoring System. The performed evaluations include:
Linearity and sensitivity, readability assessment, safety test, EMC study, vibration, software risk analysis, precision, specimen volume, interference, altitude effect, system operating condition, hematocrit, test strip and control stability (close vial and open vial), and disinfection study.
These studies and evaluations were either performed internally by professional personnel in General Life Biotechnology or were contracted to third party, performed by qualified personnel, with proper calibrated/maintained equipment and under properly-controlled environmental conditions. All of the evaluated performances passed and meet the acceptance criteria set in the study protocol.

Discussion of Clinical Tests Performed:
System Accuracy Study:
The accuracy study of the BeneCheck™ Premium GLU Monitoring System and Premium PRO GLU Monitoring System was performed by comparing whole blood (plasma equivalent) glucose values on the BeneCheck™ meter with plasma glucose values on the predicate device as well as a lab instrument.
A total of 123 subjects participated. The study result demonstrates that the accuracy of BeneCheck™ Premium GLU Monitoring System and Premium PRO GLU Monitoring System met the acceptance criteria.

User Performance Study:
A User performance study was performed to demonstrate that lay consumers could obtain accurate results using the subject device. The study was performed by 152 consumers testing capillary whole blood from fingertip, palm and forearm sample sites. The study result shows substantial equivalence to OneTouch® Ultra2 Blood Glucose Monitoring System used in finger, palm and forearm position.

510(k) SUMMARY (Cont.)

Performance:

The results of aforementioned studies demonstrate satisfactory performance of BeneCheck™ Premium GLU Monitoring System (OTC) and Premium PRO GLU Monitoring System (POC), and the device is easy to use and the results are understandable by the target users.

The following table summarizes the results from all the non-clinical testing of the BeneCheck™ Premium GLU Monitoring System and Premium PRO GLU Monitoring System.

Type of Non-Clinical Study	Acceptance Criteria; Summary of Results
Linearity	▪ R^2 of first order regression should be ≧ 0.99; **tested R^2 is 0.998, 1.000 and 0.998** ▪ Glucose concentration level should cover < 20 mg/dL & >600 mg/dL; **tested concentration ranged from 16.2 to 622 mg/dL**
Precision	▪ Overall CV (within 95% confidence interval) for both within-run and between-day should be ≦5.0% at glucose ≧75mg/dL; **all tested CV meets acceptance criteria** ▪ Standard deviation 5.0 mg/dL at glucose < 75 mg/dL; all **tested SD meets acceptance criteria**
Interference	▪ Clinically significant interference is defined as maximum bias for each individual test exceeds 10% compared to non-spike control group; **Among 26 interference substances, potential significantly interfering substances (including glutathione, levo-dopa) are described in the report and listed under 'Limitations' section of package inserts, user manuals, and labeling.**
Hematocrit (HCT) Effect	▪ Calculated % bias vs. reference value and normal HCT should be ≦ 15.0% in all tested HCT range and level of glucose ; **tested hematocrit range is 30-55%, compared to reference value 42.5% is within bias of ±15% across all glucose measuring levels**
Specimen Volume	▪ Bias of each individual test for various sample volume should be ≦ 10% compared to reference value; **bias of results are < 10% when sample volume is between 0.9 and 1.5 µL, bias is > 10% when sample volume is below 0.9 µL.**
Altitude Effect	▪ For venous blood test, bias % should be within ±10% compared to reference value at all glucose concentrations; **results from sea level to 10,498 feet (3,200 meters) indicate bias from all 3 venous blood levels are all within ±10% vs. reference value** ▪ For glucose control test, bias % of lower and upper limit of 95% CI should be within ±10% at altitude <328 feet (100 meters); **results at altitude 1,000 and 10,744 feet (3,275 meters) indicate bias within ±10%**

Type of Non-Clinical Study	Acceptance Criteria/ Summary of Results
Operating Temperature and Humidity	▪ Individual concentration bias % compared to reference value at 50~104°F (10~40°C) and 10-90% humidity should be within ±10% at all glucose concentrations; **tested results indicate individual bias compared to reference value within 10% across all 3 glucose measuring ranges.**
Test Strip Real Time Stability	▪ Individual % bias compared to reference value should be within ±10% in all 3 tested glucose levels of blood samples; **test results meet accepted criteria, on-going study for 24 months, current data indicates test strips can be stored up to 180 days at 50~86°F (10~30°C) and 10-90% humidity.**
Test Strip Accelerated Closed Vial Stability	▪ Individual % bias compared to reference value should be within ±10% in all tested three levels of blood samples; **test results meet accepted criteria, data supports claim that test strips can be stored up to 2 years at 50~86°F (10~30°C) and 10-90% humidity.**
Test Strip Open Vial Stability	▪ Individual % bias compared to reference value should be within ±10% in all tested three levels of blood samples; **test results meet accepted criteria, indicates test strips can be used (25 times) over 126 days after opening at 50~86°F (10~30°C) and 10-90% humidity.**
Control Solution Real Time Stability	▪ Individual % bias compared to reference value should be within ±10% in all 3 tested glucose levels of blood samples; **test results meet accepted criteria, on-going study for 24 months, current data indicates control solution can be stored up to 75 days at 50~86°F (10~30°C) and 10-90% humidity.**
Control Solution Accelerated Closed Vial Stability	▪ Individual % bias compared to reference value should be within ±10% in all tested three levels of blood samples; **test results meet accepted criteria, data supports claim that control solution can be stored up to 2 years at 50~86°F (10~30°C) and 10-90% humidity.**
Control Solution Open Vial Stability	▪ Individual % bias compared to reference value should be within ±10% in all tested three levels of blood samples; **test results meet accepted criteria, indicates control solution can be used (25 times) over 120 days after opening at 50~86°F (10~30°C) and 10-90% humidity.**
Disinfection Efficacy Validation Study	▪ LoD, Recovery, Interference, Neutralization, and Disinfection tests were conducted to evaluate the efficacy of disinfection procedure with specified disinfectant (Super Sani-Cloth® Germicidal Disposable Wipes) used on blood glucose meter and lancing device. Results demonstrated that HBV of clinical sera could be efficaciously removed from meter and lancing device following disinfection procedure. Results demonstrated disinfection procedure and virucide is a robust method to protect users from HBV infection.

Type of Non-Clinical Study	Acceptance Criteria/ Summary of Results
Simulation of Cleaning Cycles Study	▪ For blood glucose meter, a total 24,000 wipes (12,000 cleaning and disinfection cycles) support a minimum 3-year claim for single patient use and multiple patient professional use. Shelf life of blood glucose meter is 3 years ▪ For lancing device, a total of 160 cleaning and disinfection cycles support a minimum 3-year claim for single patient use by performing cleaning and disinfection once a week. Shelf life of lancing device is 5 years
Flesch-Kincaid Readability Assessment	▪ The operating instructions should be written at an eight-grade reading level or below to reach most of the population; **Flesch-Kincaid Grade Level Score ranges from 6.1 to 8.2 for CS Insert, Test Strip Insert, User Manual, and Quick Guide, indicating all instructions are expected to be understandable by an average student in 8th grade, therefore meeting requirement of criteria.**

Conclusion:

The results of the Clinical and Non-clinical Tests of the BeneCheck™ Premium GLU Monitoring System and Premium PRO GLU Monitoring System demonstrated that the product is safe and effectiveness in the hands of lay users (Over-The-Counter) and health care professionals (Point-of-Care). The product is substantial equivalence to the predicate device, OneTouch® Ultra2 Blood Glucose Monitoring System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 22, 2013

GENERAL LIFE BIOTECHNOLOGY CO., LTD.
C/O FENG-YU LEE
27001 LA PAZ ROAD
SUITE 266B
MISSION VIEJO CA 92691

Re: K123090
Trade/Device Name: BeneCheck Premium GLU Monitoring System
BeneCheck Premium PRO GLU Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA, JJX
Dated: November 13, 2013
Received: November 14, 2013

Dear Mrs. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

K123090

Indications for Use

510(k) Number (if known):

Device Name: BeneCheck™ Premium GLU Monitoring System

Indications For Use:

The BeneCheck™ Premium GLU Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm and forearm. The BeneCheck™ Premium GLU Monitoring System is intended to be used by a single person and should not be shared. The BeneCheck™ Premium GLU Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of a diabetes control program.

The BeneCheck™ Premium GLU Monitoring System should not be used for the diagnosis of, or screening for diabetes, nor for neonatal use. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

The BeneCheck™ Premium GLU Test Strips are for use with the BeneCheck™ Premium GLU Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm or forearm.

The BeneCheck™ Premium GLU Control Solutions are for use with the BeneCheck™ Premium GLU Meter and BeneCheck™ Premium GLU Test Strips to verify that the meters and test strips are working together properly and that the test performs properly.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE–CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Stayce Beck

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health
510(k)_____

Indications for Use

510(k) Number (if known):

Device Name: BeneCheck™ Premium PRO GLU Monitoring System

Indications For Use:

The BeneCheck™ Premium PRO GLU Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm and forearm. The BeneCheck™ Premium PRO GLU Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings, as an aid to monitor the effectiveness of a diabetes control program. The system should only be used with single-use, auto-disabling lancing devices.

The BeneCheck™ Premium PRO GLU Monitoring System should not be used for the diagnosis of, or screening for diabetes, nor for neonatal use. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

The BeneCheck™ Premium PRO GLU Test Strips are for use with the BeneCheck™ Premium GLU PRO Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm or forearm.

The BeneCheck™ Premium PRO GLU Control Solutions are for use with the BeneCheck™ Premium PRO GLU Meter and BeneCheck™ Premium PRO GLU Test Strips to verify that the meters and test strips are working together properly and that the test performs properly.

Prescription Use ___ X ___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE–CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Division Sign-Off

Stayce Beck

Office of In Vitro Diagnostics and Radiological Health

510(k)_____